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10/538,442	09/11/2006	Jean Pierre Gayral	GENOM.061np	3808

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EXAMINER	
WILDER, CYNTHIA B	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,442	GAYRAL ET AL.	
	Examiner	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) *1-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-14, drawn to a reagent.

Group II, claim(s) 15-46, drawn to a method for verifying the efficiency of sample preparation.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The claims of Group I are sufficiently broad to encompass a reagent taught in the prior art. Accordingly, the invention does not represent a contribution over the prior art because the art teaches a reagent (see Ke et al., Clinical Chemistry, vol. 43, no. 3, pages 324-331, 2000, especially page 325, col. 2) as required by the invention of Group I. The claims lack a special technical feature that is the same or that corresponds to a special feature of the other claimed invention. Thus, there is not a special technical feature linking the recited groups, as would be necessary to fulfill the requirements for unity of invention.

Further Groups I-II are drawn to distinct inventions in that the reagent of Group I can function irrespective of the method for determining efficiency of a sample preparation via a PCR amplification reaction and visa versa. A search burden exists if

the different inventions are search together because the searches of the different inventions are not coextensive. Specifically, a search of the invention of Group I would encompass a search of numerous patent and non-patent literature documents irregardless of its use in any method especially the method for verifying the efficiency of a sample preparation as claimed in the invention of Group II. Furthermore, prior art which may teach the reagent, may not necessarily be applicable to the method for verifying efficiency of a sample preparation as claimed in the invention of Group II. Moreover, even if the reagent were known, the method of using the reagent may be novel and unobvious in view of the preamble and active steps. The different inventions are patentably distinct requiring different fields of search.

2. During a telephone conversation with Mr. Israelsen on April 19, 2007 a provisional election was made with traverse to prosecute the invention of Group II, claims 15-46. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-14 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

4. The specification is objected for following informalities: The use of the trademark "Genie2 model vortex" at page 34, "Taqstart" and "Smart Cycler" at page 44 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

35 USC 112 second paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 15-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claims 15-46 are indefinite in the claims 15 and 32 are indefinite in the final process step because the preamble recites a method for verifying the efficiency of a sample preparation, however the final process step recites releasing, purifying or concentrating nucleic acids in a test sample and added reagent and submitting the released, purified and/or concentrated nucleic acid to amplification or detection. Thus, it cannot be determined if the goal of the preamble is achieved and if so, in what step. While minute details are not required in method claims, at least the basic steps must be

recited in a positive, active fashion (see *ex parte Erlich*, 3 UsPQ2d1011, p.1011 (Bd. Pat, Applicant. Int.1986). Clarification is required as to Applicant's intent.

(b) Claims 28 and 44 are confusing at " a 10 sample of clinical, environmental or alimentary origin" because it unclear what is meant by "a 10 sample". Specifically, it is unclear if Applicant is suggesting that the sample comprise a total of 10 test samples to be analyzed that are from each of a clinical environmental or alimentary origin or if applicant is suggesting a desired name, property or characteristic for the test sample or something completely different. Clarification is required.

Claim Rejections - 35 USC § 102(b)

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 15, 16, 18-21, 23-29, 31-32, 34-37, 39-45 are rejected under 35 USC 102(b) as being anticipated by Ke et al (Clinical Chemistry, vol. 46, no. 3, pages 324-331, 2000). Regarding claims 15 and 32, Ke et al teach a method comprising providing a reagent comprising a cell comprising a bacterial cells comprising at least one nucleic acid sequence serving as an internal control target sample preparation; adding said reagent into said test sample; submitting said released, nucleic acid to amplification or detection (page 325, "construction of the internal control" and "PCR amplification"; see also "Table 3").

Regarding claim 16, Ke et al teach a method as defined in claim 15, further comprising comparing the amplification and/or detection performed in iv) to the amplification and/or detection performed with control reaction to evaluate the efficiency of sample preparation ("PCR amplification" and "Specificity and Sensitivity tests").

Regarding claims 18 and 34, Ke et al teach the method of claims 15 or 16, wherein said cells is bacteria (Table 1).

Regarding the claims 19 and 35, Ke et al teach the method of claims 15 or 16, wherein said cells is *E. coli* (page 325, col. 2, "construction of the internal control" and Table 1).

Regarding claims 20 and 36, Ke et al teach the method of claims 15 or 16, wherein said cells are bacterial spores (Table 1).

Regarding claims 21, and 37, Ke et al teach the method of claims 15 or 16, wherein said cells are bacterial spores such as Bacillus anthracis (page 326, Table 1).

Regarding claims 23 and 39, Ke et al teach the method of claims 15 or 16, wherein said IC target nucleic acid sequence is on a cloning vector (page 325, col. 2, "construction of the internal control").

Regarding claims 24 and 40, Ke et al teach the method of claims 23 or 39, wherein said IC target nucleic acid sequence is on a plasmid vector (page 325, col. 2, "construction of the internal control").

Regarding claims 25 and 41, Ke et al teach the method of claim 15, wherein said nucleic acid amplification method is PCR ("PCR amplification"; see also "Table 3").

Regarding claims 26 and 42, Ke et al teach the method of claim 15, wherein said IC nucleic acid sequence is a nucleic acid sequence of clinical origin and of human origin (page 325, col. 1, section entitled "Microorganisms" and "DNA Isolation").

Regarding claim 27 and 43, Ke et al teach the method of claim 15, wherein the IC target nucleic acid sequence is a nucleic acid sequence of microbial origin (see page 325, section entitled "Microorganisms" and "DNA Isolation").

Note* For the purpose of application of prior art, the claimed limitation "a 10 sample" is being interpreted by the Examiner as a minimum amount of samples to be analyzed by the method. Regarding claims 28 and 44, Ke et al teach the method of claim 15, wherein the test sample comprises over 10 samples of clinical origin (page 327, "clinical specimens and GBS-selective culture and PCR").

Regarding claims 29 and 45, Ke et al teach wherein the test sample comprises a vaginal/anal swab (page 327, "clinical specimens and GBS-selective culture and PCR" and Table 1).

Regarding claim 31, Ke et al teach the method of claim 15, wherein said reagent may be a bacterial spore which allows one to determine the efficiency of the sample preparation (see Table 1). Therefore, Ke et al meet the limitations of the claims recited above.

Claim Rejections - 35 USC § 102

9. Claims 15-17, 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Saldanha, John (Journal of Clinical Virology, vol. 20, pages 7-13, January 2001). Regarding claims 15 and 32, Saldanha teaches a method comprising providing a reagent comprising a cell comprising a viral particle comprising at least one nucleic acid sequence serving as an internal control target sample preparation; adding said reagent into said test sample; submitting said released, nucleic acid to amplification or detection to determine efficiency of the sample preparation (abstract and page 11-12, "Quality control of NAT assays").

Regarding claim 16, Saldanha teaches further comprising comparing the amplification and/or detection performed in iv) to the amplification and/or detection performed with control reaction to evaluate the efficiency of sample preparation (page 8-10, sections 2 and 3 and Tables 1-3).

Regarding claim 17 and 33, Saldanha teaches wherein said sample preparation procedures comprise concentrating said cells comprising viral particles prior to lysis (abstract and section entitled "development of working reagents"). Therefore Saldanha meets the limitations of the claims recited above.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claims 15-21, 30, 32-34, 36, 37, 46 are rejected under 35 U.S.C. 102(a) as being anticipated by Picard and Bergeron (Drug Discovery Today, vol. 7, Issue 2, pages 1092-1101, November 2002). Regarding claims 15, 16 and 32, Picard and Bergeron teach a method comprising providing a reagent comprising a cell comprising a bacterial cells comprising at least one nucleic acid sequence serving as an internal control target sample preparation; adding said reagent into said test sample; submitting said released, nucleic acid to amplification or detection and further comparing the amplification and/or detection with control reactions to evaluate the efficiency of the sample preparation (see sections 2.2 and 2.5-2.5.3.).

Regarding claims 17 and 33, Picard and Bergeron teach wherein said sample preparation comprises purifying the cells prior to lysis (section 2.2).

Regarding claims 18 and 34, Picard and Bergeron teach wherein said cell is selected from bacteria (section 2.2).

Regarding claim 20, 21, 36 and 37, Picard and Bergeron teach wherein said cell are bacillus spores (section 2.2).

Regarding claim 30 and 46, Picard and Bergeron teach wherein the sample preparation comprises concentrating and purifying cells or viral particles lysis of cells, nucleic acid extraction, inactivation, elimination or neutralization of Nat inhibitors and or

nucleic acid concentration or purification (see section 2.2 and 2.5 to 2.5.2). Therefore, Picard and Bergeron meet the limitations of the claims as recited above.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 21 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ke et al as previously applied above in view of Kuske et al (Applied and Environmental Microbiology, July 1998, vol. 64, no. 7, pages 2463-2472). Regarding claims 21 and 37, Ke et al teach a method for verifying the efficiency of sample preparation as previously discussed above, wherein said method comprises providing a reagent comprising a cell wherein said cell may be bacterial spores and wherein said

cell comprises at least one nucleic acid serving as an internal control target sample preparation.

Ke et al differs from the instant invention in that the reference does not teach wherein the bacterial spores are *Bacillus globigii* spores.

Kuske et al teach a method for determining the efficiencies of a sample preparation for PCR amplification and detection wherein said sample is an environmental sample comprising cells of Bacillus globigii endospores (see Material and Methods and page 2471, last paragraph of col. 1 bridging first two paragraphs of col. II). Kuske et al teach that there is a need for detecting microbial cells and spores in soil or environmental samples. Kuske et al teaches that while the art provides methods for extracting DNA from microbial spores in soil, the spore forming bacterial DNA is often severely sheared and does not provide for the highest PCR detection sensitivity (page 2463, col. 2). Kuske additionally teaches that environmental samples, which may comprise spore-forming bacterial cells, are often difficult to obtain, may be present in very low concentrations and/or partially degraded or compromised by chemical treatment (page 2471). Therefore, in view of the foregoing one of ordinary skill in the art at the time of the claimed invention would have been motivated to have modified the method of Ke et al to encompass other spore forming bacterial microbes such as *B. Globiggi* et al for the benefit of increases sensitivity of PCR detection of environmental samples as suggested by Kuske. One of ordinary skill in the art would have been motivated to do so based on the need in the art as taught by Kuske for detecting microbial DNA from environmental samples, such as soil.

Conclusion

15. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cynthia Wilder

Cynthia B. Wilder, Ph.D.
Patent Examiner
Art Unit 1637

5/4/2007